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Histamine H₂-Receptor Antagonists (Systemic)

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Brand Names

Some commonly used brand names are:

In the U.S.--

- Axid³
- Axid AR³
- Mylanta AR Acid Reducer²
- Pepcid²
- Pepcid I.V.²
- Pepcid AC Acid Controller²
- Pepcid RPD²
- Tagamet¹
- Tagamet HB¹
- Zantac⁴
- Zantac EFFERdose Granules⁴
- Zantac EFFERdose Tablets⁴

In Canada--

- Acid Control²
- Act²
- Apo-Cimetidine¹
- Apo-Famotidine²
- Apo-Nizatidine³

- Apo-Ranitidine ⁴
- Axid ³
- Dyspep HB ²
- Gen-Cimetidine ¹
- Gen-Famotidine ²
- Gen-Ranitidine ⁴
- Maalox H2 Acid Controller ²
- Novo-Cimetidine ¹
- Novo-Famotidine ²
- Novo-Ranitidine ⁴
- Nu-Cimet ¹
- Nu-Famotidine ²
- Nu-Ranit ⁴
- Pepcid ²
- Pepcid AC ²
- Pepcid I.V. ²
- Peptol ¹
- PMS-Cimetidine ¹
- Tagamet ¹
- Ulcidine ²
- Ulcidine-HB ²
- Zantac ⁴
- Zantac 75 ⁴

Note:	For quick reference, the following histamine H ₂ -receptor antagonists are numbered to match the corresponding brand names.
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This information applies to the following medicines:

1. Cimetidine (sy-MET-i-deen)\$&
2. Famotidine (fa-MOE-ti-deen)&
3. Nizatidine (ni-ZA-ti-deen)
4. Ranitidine (ra-NIT-ti-deen)\$

\$ Generic name product may be available in the

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Category

- **Histamine H₂-receptor antagonist**--Cimetidine; Famotidine; Nizatidine; Ranitidine
- **Antiulcer agent**--Cimetidine; Famotidine; Nizatidine; Ranitidine
- **Gastric acid secretion inhibitor**--Cimetidine; Famotidine; Nizatidine; Ranitidine
- **Urticaria therapy adjunct**--Cimetidine

Description

Histamine H₂-receptor antagonists, also known as H₂-blockers, are used to treat duodenal ulcers and prevent their return. They are also used to treat gastric ulcers and for some conditions, such as Zollinger-Ellison disease, in which the stomach produces too much acid. In over-the-counter (OTC) strengths, these medicines are used to relieve and/or prevent heartburn, acid indigestion, and sour stomach. H₂-blockers may also be used for other conditions as determined by your doctor.

H₂-blockers work by decreasing the amount of acid produced by the stomach.

They are available in the following dosage forms:

Oral

- Cimetidine
 - Oral solution (U.S. and Canada)
 - Tablets (U.S. and Canada)
- Famotidine
 - Oral suspension (U.S.)
 - Tablets (U.S. and Canada)
 - Chewable tablets (U.S. and Canada)
 - Oral disintegrating tablets (U.S.)
- Nizatidine
 - Capsules (U.S. and Canada)
 - Tablets (U.S.)
- Ranitidine
 - Effervescent granules (U.S.)
 - Syrup (U.S. and Canada)
 - Tablets (U.S. and Canada)
 - Effervescent tablets (U.S.)

Parenteral

- Cimetidine
 - Injection (U.S. and Canada)
- Famotidine
 - Injection (U.S. and Canada)
- Ranitidine
 - Injection (U.S. and Canada)

Before Using This Medicine

In deciding to use a medicine, the risks of taking the medicine must be weighed against the good it will do. This is a decision you and your doctor will make. For H₂-blockers, the following should be considered:

Allergies--Tell your doctor if you have ever had any unusual or allergic reaction to cimetidine, famotidine, nizatidine, or ranitidine.

Pregnancy--H₂-blockers have not been studied in pregnant women. In animal studies, famotidine and ranitidine have not been shown to cause birth defects or other problems. However, one study in rats suggested that cimetidine may affect male sexual development. More studies are needed to confirm this. Also, studies in rabbits with very high doses have shown that nizatidine causes miscarriages and low birth weights. Make sure your doctor knows if you are pregnant or if you may become pregnant before taking H₂-blockers.

Breast-feeding--Cimetidine, famotidine, nizatidine, and ranitidine pass into the breast milk and may cause unwanted effects, such as decreased amount of stomach acid and increased excitement, in the nursing baby. It may be necessary for you to take another medicine or to stop breast-feeding during treatment. Be sure you have discussed the risks and benefits of the medicine with your doctor.

Children--This medicine has been tested in children and, in effective doses, has not been shown to cause different side effects or problems than it does in adults when used for short periods of time.

Older adults--Confusion and dizziness may be especially likely to occur in elderly patients, who are usually more sensitive than younger adults to the effects of H₂-blockers.

Other medicines--Although certain medicines should not be used together at all, in other cases two different medicines may be used together even if an interaction might occur. In these cases, your doctor may want to change the dose, or other precautions may be necessary. When you are taking or receiving H₂-blockers it is especially important that your health care professional know if you are taking any of the following:

- Aminophylline (e.g., Somophyllin) or
- Anticoagulants (blood thinners) or
- Caffeine (e.g., NoDoz) or
- Metoprolol (e.g., Lopressor) or
- Oxtriphylline (e.g., Choledyl) or
- Phenytoin (e.g., Dilantin) or
- Propranolol (e.g., Inderal) or
- Theophylline (e.g., Somophyllin-T) or
- Tricyclic antidepressants (amitriptyline [e.g., Elavil], amoxapine [e.g., Asendin], clomipramine [e.g., Anafranil], desipramine [e.g., Pertofrane], doxepin [e.g., Sinequan], imipramine [e.g., Tofranil], nortriptyline [e.g., Aventyl], protriptyline [e.g., Vivactil], trimipramine [e.g., Surmontil])--Use of these medicines with cimetidine has been shown to increase the effects of cimetidine. This is less of a problem with ranitidine and has not been reported for famotidine or nizatidine. However, all of the H₂-blockers are similar, so drug interactions may occur with any of them
- Itraconazole (e.g., Sporanox) or
- Ketoconazole (e.g., Nizoral)--H₂-blockers may decrease the effects of itraconazole or ketoconazole; H₂-blockers should be taken at least 2 hours after these medicines

Other medical problems--The presence of other medical problems may affect the use of H₂-blockers. Make sure you tell your doctor if you have any other medical problems, especially:

- Kidney disease or
- Liver disease--The H₂-blocker may build up in the bloodstream, which may increase the risk of side effects
- Phenylketonuria (PKU)--Some H₂-blockers contain aspartame. Aspartame is converted to phenylalanine in the body and must be used with caution in patients with PKU. The Pepcid AC brand of famotidine chewable tablets contains 1.4 mg of phenylalanine per 10-mg dose. The Pepcid RPD brand of famotidine oral dispersible tablets contains 1.05 mg of phenylalanine per 20-mg dose. The Zantac brand of ranitidine EFFERdose tablets and EFFERdose granules contain 16.84 mg of phenylalanine per 150-mg dose
- Weakened immune system (difficulty fighting infection)--Decrease in stomach acid caused by H₂-blockers may increase the possibility of a certain type of infection

Proper Use of This Medicine

For patients taking the *nonprescription strengths* of these medicines for heartburn, acid indigestion, and sour stomach:

- Do not take the maximum daily dosage continuously for more than 2 weeks, unless directed to do so by your doctor.
- If you have trouble in swallowing, or persistent abdominal pain, see your doctor promptly. These may be signs of a serious condition that may need different treatment.

For patients taking the *prescription strengths* of these medicines for more serious problems:

- One dose a day--Take it at bedtime, unless otherwise directed.
- Two doses a day--Take one in the morning and one at bedtime.
- Several doses a day--Take them with meals and at bedtime for best results.

It may take several days before this medicine begins to relieve stomach pain. To help relieve this pain, antacids may be taken with the H₂-blocker, unless your doctor has told you not to use them. However, you should wait one-half to one hour between taking the antacid and the H₂-blocker.

Take this medicine for the full time of treatment, even if you begin to feel better. Also, it is important that you keep your appointments with your doctor for check-ups so that your doctor will be better able to tell you when to stop taking this medicine.

For patients taking *famotidine chewable tablets* :

- Chew the tablets well before swallowing.

For patients taking *famotidine oral disintegrating tablets* :

- Make sure your hands are dry.
- Leave tablets in unopened package until the time of use, then open the pack and remove

the tablet.

- Immediately place the tablet on the tongue.
- The tablet will dissolve in seconds, and you may swallow it with your saliva. You do not need to drink water or other liquid to swallow the tablet.

For patients taking *ranitidine effervescent granules or tablets* :

- Remove the foil wrapping and dissolve the dose in 6 to 8 ounces of water before drinking.

Dosing--The dose of histamine H₂-receptor antagonists (also called H₂-blockers) will be different for different patients. *Follow your doctor's orders or the directions on the label* . The following information includes only the average doses of these medicines. *If your dose is different, do not change it unless your doctor tells you to do so* .

The number of capsules or tablets or teaspoonfuls of solution, suspension, or syrup that you take depends on the strength of the medicine. Also, *the number of doses you take each day, the time allowed between doses, and the length of time you take the medicine depend on the medical problem for which you are taking the H₂-receptor antagonist* .

For cimetidine

- For oral dosage forms (solution and tablets):
 - To treat duodenal or gastric ulcers:
 - Older adults, adults, and teenagers--300 milligrams (mg) four times a day, with meals and at bedtime. Some people may take 400 or 600 mg two times a day, on waking up and at bedtime. Others may take 800 mg at bedtime.
 - Children--20 to 40 mg per kilogram (kg) (9.1 to 18.2 mg per pound) of body weight a day, divided into four doses, taken with meals and at bedtime.
 - To prevent duodenal ulcers:
 - Older adults, adults, and teenagers--300 mg two times a day, on waking up and at bedtime. Instead some people may take 400 mg at bedtime.
 - Children--Dose must be determined by your doctor.
 - To treat heartburn, acid indigestion, and sour stomach:
 - Adults and teenagers--100 to 200 mg with water when symptoms start. The dose may be repeated once in twenty-four hours. Do not take more than 400 mg in twenty-four hours.
 - Children--Dose must be determined by your doctor.
 - To prevent heartburn, acid indigestion, and sour stomach:
 - Adults and teenagers--100 to 200 mg with water up to one hour before eating food or drinking beverages you expect to cause symptoms. Do not take more than 400 mg in twenty-four hours.
 - Children--Dose must be determined by your doctor.
 - To treat conditions in which the stomach produces too much acid:
 - Adults--300 mg four times a day, with meals and at bedtime. Your doctor may change the dose if needed.
 - Children--Dose must be determined by your doctor.
 - To treat gastroesophageal reflux disease:
 - Adults--800 to 1600 mg a day, divided into smaller doses. Treatment usually lasts for 12 weeks.
 - Children--Dose must be determined by your doctor.

- For *injectable* dosage form:
 - To treat duodenal ulcers, gastric ulcers or conditions in which the stomach produces too much acid:
 - Older adults, adults, and teenagers--300 mg injected into muscle, every six to eight hours. Or, 300 mg injected slowly into a vein every six to eight hours. Instead, 900 mg may be injected slowly into a vein around the clock at the rate of 37.5 mg per hour. Some people may need 150 mg at first, before beginning the around-the-clock treatment.
 - Children--5 to 10 mg per kg (2.3 to 4.5 mg per pound) of body weight injected into a vein or muscle, every six to eight hours.
 - To prevent stress-related bleeding:
 - Older adults, adults, and teenagers--50 mg per hour injected slowly into a vein around the clock for up to 7 days.
 - Children--Dose must be determined by your doctor.

For famotidine

- For *oral* dosage forms (suspension, tablets, chewable tablets, and oral disintegrating tablets):
 - To treat duodenal ulcers:
 - Older adults, adults, and teenagers--40 milligrams (mg) once a day at bedtime. Some people may take 20 mg two times day.
 - Children--Dose must be determined by your doctor.
 - To prevent duodenal ulcers:
 - Older adults, adults, and teenagers--20 mg once a day at bedtime.
 - Children--Dose must be determined by your doctor.
 - To treat gastric ulcers:
 - Older adults, adults, and teenagers--40 mg once a day at bedtime.
 - Children--Dose must be determined by your doctor.
 - To treat heartburn, acid indigestion, and sour stomach:
 - Adults and teenagers--10 mg with water when symptoms start. The dose may be repeated once in twenty-four hours. Do not take more than 20 mg in twenty-four hours.
 - Children--Dose must be determined by your doctor.
 - To prevent heartburn, acid indigestion, and sour stomach:
 - Adults and teenagers--10 mg taken one hour before eating a meal you expect to cause symptoms. The dose may be repeated once in twenty-four hours. Do not take more than 20 mg in twenty-four hours.
 - Children--Dose must be determined by your doctor.
 - To treat conditions in which the stomach produces too much acid:
 - Older adults, adults, and children--20 mg every six hours. Your doctor may change the dose if needed.
 - Children--Dose must be determined by your doctor.
 - To treat gastroesophageal reflux disease:
 - Older adults, adults, and teenagers--20 mg two times a day, usually for up to 6 weeks.
 - Children weighing more than 10 kg (22 pounds)--1 to 2 mg per kilogram (kg) (0.5 to 0.9 mg per pound) of body weight a day divided into two doses.
 - Children weighing less than 10 kg (22 pounds)--1 to 2 mg per kg (0.5 to 0.9 mg per pound) of body weight a day, divided into three doses.
- For *injectable* dosage form:

- To treat duodenal ulcers, gastric ulcers, or conditions in which the stomach produces too much acid:
 - Older adults, adults, and teenagers--20 mg injected into a vein, every twelve hours.
 - Children--Dose must be determined by your doctor.

For nizatidine

- For *oral* dosage forms (capsules and tablets):
 - To treat duodenal or gastric ulcers:
 - Older adults, adults, and teenagers--300 milligrams (mg) once a day at bedtime. Some people may take 150 mg two times a day.
 - Children--Dose must be determined by your doctor.
 - To prevent duodenal ulcers:
 - Adults and teenagers--150 mg once a day at bedtime.
 - Children--Dose must be determined by your doctor.
 - To prevent heartburn, acid indigestion, and sour stomach:
 - Adults and teenagers--75 mg taken thirty to sixty minutes before eating a meal you expect to cause symptoms. The dose may be repeated once in twenty-four hours.
 - Children--Dose must be determined by your doctor.
 - To treat gastroesophageal reflux disease:
 - Adults and teenagers--150 mg two times a day.
 - Children--Dose must be determined by your doctor.

For ranitidine

- For *oral* dosage forms (effervescent granules, syrup, tablets, effervescent tablets):
 - To treat duodenal ulcers:
 - Older adults, adults, and teenagers--150 milligrams (mg) two times a day. Some people may take 300 mg once a day at bedtime.
 - Children--2 to 4 mg per kilogram (kg) (1 to 2 mg per pound) of body weight per day, usually given as two divided doses. However, your total dose will not be more than 300 mg a day.
 - To prevent duodenal ulcers:
 - Older adults, adults, and teenagers--150 mg at bedtime.
 - Children--Dose must be determined by your doctor.
 - To treat gastric ulcers:
 - Older adults, adults, and teenagers--150 mg two times a day.
 - Children--2 to 4 mg per kilogram (1 to 2 mg per pound) of body weight per day, usually given as two divided doses. However, your total dose will not be more than 300 mg a day.
 - To treat heartburn, acid indigestion, and sour stomach:
 - Adults and teenagers--75 mg with water when symptoms start. The dose may be repeated once in twenty-four hours. Do not take more than 150 mg in twenty-four hours.
 - Children--Dose must be determined by your doctor.
 - To prevent heartburn, acid indigestion, and sour stomach:
 - Adults and teenagers--75 mg with water taken thirty to sixty minutes before eating a meal or drinking beverages you expect to cause symptoms. Do not take more than 150 mg in twenty-four hours.
 - Children--Dose must be determined by your doctor.

- To treat some conditions in which the stomach produces too much acid:
 - Older adults, adults, and teenagers--150 mg two times a day. Your doctor may change the dose if needed.
 - Children--Dose must be determined by your doctor.
- To treat gastroesophageal reflux disease:
 - Older adults, adults, and teenagers--150 mg two times a day. Your dose may be increased if needed.
 - Children--5 to 10 mg per kg (2.3 to 4.6 mg per pound) of body weight a day, usually divided and given in two doses during the day. However, most children usually will not take more than 300 mg a day.
- For *injectable* dosage form:
 - To treat duodenal ulcers, gastric ulcers, or conditions in which the stomach produces too much acid:
 - Older adults, adults, and teenagers--50 mg injected into a muscle every six to eight hours. Or, 50 mg injected slowly into a vein every six to eight hours. Instead, you may receive 6.25 mg per hour injected slowly into a vein around the clock. However, most people will usually not need more than 400 mg a day.
 - To treat duodenal or gastric ulcers:
 - Children--2 to 4 mg per kg (1 to 2 mg per pound) of body weight a day, injected slowly into a vein.

Missed dose--If you miss a dose of this medicine, take it as soon as possible. However, if it is almost time for your next dose, skip the missed dose and go back to your regular dosing schedule. Do not double doses.

Storage--To store this medicine:

- Keep out of the reach of children.
- Store away from heat and direct light.
- Do not store the capsule or tablet form of this medicine in the bathroom, near the kitchen sink, or in other damp places. Heat or moisture may cause the medicine to break down.
- Keep the liquid form of this medicine from freezing.
- Do not keep outdated medicine or medicine no longer needed. Be sure that any discarded medicine is out of the reach of children.

Precautions While Using This Medicine

Some tests may be affected by this medicine. Tell the doctor in charge that you are taking this medicine before:

- You have any skin tests for allergies.
- You have any tests to determine how much acid your stomach produces.

Remember that certain medicines, such as aspirin, and certain foods and drinks (e.g., citrus products, carbonated drinks, etc.) irritate the stomach and may make your problem worse.

Cigarette smoking tends to decrease the effect of H₂-blockers by increasing the amount of acid produced by the stomach. This is more likely to affect the stomach's nighttime production

of acid. While taking H₂-blockers, stop smoking completely, or at least do not smoke after taking the last dose of the day.

Drinking alcoholic beverages while taking an H₂-receptor antagonist has been reported to increase the blood levels of alcohol. You should consult your health care professional for guidance.

Check with your doctor if your ulcer pain continues or gets worse.

Side Effects of This Medicine

Along with its needed effects, a medicine may cause some unwanted effects. Although not all of these side effects may occur, if they do occur they may need medical attention.

Check with your doctor as soon as possible if any of the following side effects occur:

Rare

Abdominal pain; back, leg, or stomach pain; bleeding or crusting sores on lips; blistering, burning, redness, scaling, or tenderness of skin; blisters on palms of hands and soles of feet; changes in vision or blurred vision; confusion; coughing or difficulty in swallowing; dark-colored urine; dizziness; fainting; fast, pounding, or irregular heartbeat; fever and/or chills; flu-like symptoms; general feeling of discomfort or illness; hives; inflammation of blood vessels; joint pain; light-colored stools; mood or mental changes, including anxiety, agitation, confusion, hallucinations (seeing, hearing, or feeling things that are not there), mental depression, nervousness, or severe mental illness; muscle cramps or aches; nausea, vomiting, or loss of appetite; pain; peeling or sloughing of skin; red or irritated eyes; shortness of breath; skin rash or itching; slow heartbeat; sore throat; sores, ulcers, or white spots on lips, in mouth, or on genitals; sudden difficult breathing; swelling of face, lips, mouth, tongue, or eyelids; swelling of hands or feet; swollen or painful glands; tightness in chest; troubled breathing; unusual bleeding or bruising; unusual tiredness or weakness; unusually slow or irregular breathing; wheezing; yellow eyes or skin

Other side effects may occur that usually do not need medical attention. These side effects may go away during treatment as your body adjusts to the medicine. However, check with your doctor if any of the following side effects continue or are bothersome:

Less common or rare

Constipation; decreased sexual ability (especially in patients with Zollinger-Ellison disease who have received high doses of cimetidine for at least 1 year); decrease in sexual desire; diarrhea; difficult urination; dizziness; drowsiness; dryness of mouth or skin; headache; increased or decreased urination; increased sweating; loss of hair; ringing or buzzing in ears; runny nose; swelling of breasts or breast soreness in females and males; trouble in sleeping

Not all of the side effects listed above have been reported for each of these medicines, but they have been reported for at least one of them. All of the H₂-blockers are similar, so any of the above side effects may occur with any of these medicines.

Other side effects not listed above may also occur in some patients. If you notice any other effects, check with your doctor.

Additional Information

Once a medicine has been approved for marketing for a certain use, experience may show that it is also useful for other medical problems. Although these uses are not included in product labeling, H₂-blockers are used in certain patients with the following medical conditions:

- Damage to the stomach and/or intestines due to stress or trauma
- Hives
- Pancreatic problems
- Stomach or intestinal ulcers (sores) resulting from damage caused by medication used to treat rheumatoid arthritis

Other than the above information, there is no additional information relating to proper use, precautions, or side effects for these uses.

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